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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: AVIVI=1A

PH#3

In re Application of:)	Art Unit:
Lydia AVIAI et al.)	Examiner:
Appln. No.: 09/660,328)	Washington, D.C.
Filed: September 12, 2000)	March 22, 2002
For: FACILE DETECTION OF CANCER))	
AND CANCER RISK BASED ON...))	

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INFORMATION DISCLOSURE STATEMENT [IDS]

Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir :

This Information Disclosure Statement is submitted in accordance with 37 CFR §§1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

[X] 1. This IDS should be considered, in accordance with 37 CFR §1.97, as it is filed:

(Check one of the boxes A-D)

[] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application.

☒ B. before the mailing date of a first office action on the merits.

☐ C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below).

(Check one of the boxes "i" and "ii" below:)

☐ i. Counsel certifies that, upon information and belief, each item of information listed herein was either

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of undersigned after making reasonable inquiry, was not known to any individual designated in §1.56(c) more than three months prior to the filing of this IDS.

(use one and delete other of following)

☐ ii. A check (check no. _____) for the fee set forth in §1.17(p), presently believed to be \$180, is enclosed.

☐ ii. Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in §1.17(p), presently believed to be \$180.

☐ D. after (A), (B) and (C) above, but before payment of the issue fee: Applicant(s) petitions under 37 CFR §1.97(d) for consideration of this IDS. ***(use one and delete***

other of following and this note) A check (check no. _____) for/ Credit Card Payment Form, PTO-2038, is attached authorizing payment of the fee set forth in \$1.17(i), presently believed to be \$130 is enclosed. Counsel certifies that, upon information and belief, each item of information listed herein was either

(Check one of the boxes "a" and "b" below)

☐ (a) first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was not known to any individual designated in \$1.56(c) more than three months prior to the filing of this IDS.

☒ 2. In accordance with 37 CFR \$1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document listed is attached, except as explained below.

(check boxes A and/or B and fill in blanks, if appropriate)

☐ A. Document(s) _____ is (are) deemed substantially cumulative to document(s) _____, and, in accordance with \$1.98(c), only a copy of each of the latter documents is enclosed.

☒ B. Documents AA-BW were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

09/345,029 filed July 2, 1999

Applicant(s) identifies these documents by attaching hereto copies of the forms PTO-892 and PTO-1449 from the files of the prior application(s) or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with §1.98(d). Per 37 CFR §1.98(d), copies of these documents need not be filed in this application.

☐ 3. Document(s) _____ is (are) not in the English language. In accordance with §1.98(c), Applicant(s) states:

☐ An English translation of each document _____ (or of the pertinent portions thereof), or a copy of each corresponding English-language patent or application, or English-language abstract (or claim) is enclosed.

☐ A concise explanation of the relevance of document(s) _____ is found in the attached _____ search report (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ A concise explanation of the relevance of document(s) _____ is set forth as follows:

(insert concise explanation of relevance)

☐ A concise explanation of the relevance of document(s) _____ can be found on page(s) _____ of the specification.

☐ A concise explanation of document(s) _____ can be found on the attached sheet.

[X] 4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

[] 5. Other information being provided for the examiner's consideration follows:

(insert other information)

6. In accordance with 37 CFR §§1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant(s) reserves the right to prove that the date of publication is in fact different.

Respectfully submitted,

BROWDY AND NEIMARK
Attorneys for Applicant(s)

By: 

Allen C. Yun
Reg. No. 37,971

624 Ninth Street, N.W., Suite 300
Washington, D.C. 20001-5303
Telephone: (202) 628-5197
Facsimile: (202) 737-3528

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of

1

Complete if Known

Application Number	09/660,328
Filing Date	September 20, 2000
First Named Inventor	AVIVI et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	AVIVI=1A

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	
AA	Amiel A., Korenstein A., Gaber E., Avivi, L., "Asynchronous replication of alleles in genomes carrying an extra autosome", EUROPEAN JOURNAL OF HUMAN GENETICS 7, 223-230 (1999)		
AB	Atkins L., Taft P., Kalal K., "Asynchronous DNA synthesis of sex chromatin in human interphase nuclei", J BIOL, 15:390-393 (1962)		
AC	Avivi L., Dotan A., Ravia Y., Amiel A., Schacham h., Neumann Y. "Increased spindle resistance to antimicrotubule agents in cells prone to chromosomal nondisjunction", HUMAN GENET, 83:165-170 (1989)		
AD	Boggs, B., Chinault A., "Analysis of the replication timing properties of human X-chromosomal loci by fluorescence <i>in-situ</i> hybridization", PROC. NATL. ACAD. SCI. USA, 91:6083-6087 (1994)		
AE	Boggs, B., Chinault A., "Analysis of DNA replication by fluorescence <i>in situ</i> hybridization", METHODS, 13:259-270 (1997)		
AF	Chess A., "Expansion of the allelic exclusion principle?", SCIENCE 279:2067-2068 (1998)		
AG	Chess A., Simon I., Cedar H., Axel R., "Allelic inactivation regulates olfactory receptor gene expression", CELL 78:823-834 (1994)		
AH	Cui h., Horon I., Ohlsson R., Hamilton S., Feinberg A., "Loss of imprinting in normal tissue of colorectal cancer patients with microsatellite instability", NAT MED 4:1276-1280 (1998)		
AI	Dhar V., Magar D., Iqbal A., Schildraut C., "The coordinate replication of the human β -globin gene domain reflects its transcriptional activity and nuclease hypersensitivity", MOL CELL BIOL 8:4958-4965 (1988)		
AJ	Dhar V., Skoultschi A., Schildraut C., "Activation and repression of a β -globin gene in cell hybrids is accompanied by a shift in its temporal replication", MOL CEL BIOL 9:3524-3532 (1989)		
AK	Dotan Z., Dotan A., Imanovitch T., Ravia Y., Oniashvili N., Leibovitch I., Ramon J., Avivi L., "Allele-specific mode of replication in peripheral lymphocytes of renal cell carcinoma patients: A new aspect of genomic instability", Annual Meeting at the American Urological Association, May 1999, Dallas, Texas.		
AL	Dotan Z., Dotan A., Imanovitch T., Ravia Y., Oniashvili N., Leibovitch I., Ramon J., Avivi L., "Allele-specific mode of replication in peripheral lymphocytes of renal cell carcinoma patients: A new aspect of genomic instability - a possible clinical use - part II", Annual Meeting at the American Urological Association, Eilat, Israel, Nov. 1998		
AM	Epner E., Forrester W., Groudine M., "Asynchronous DNA replication within the human β -globin gene", PROC NATL ACAD SCI USA, 85:8081-8085 (1988)		

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

AN	Feinberg A., "Genomic imprinting and cancer", THE GENETIC BASIS OF HUMAN CANCER, Vogelstein B., Kinzler L., eds., McGraw-hill, New York pp. 95-107 (1998)	
AO	Goldman, M., holmquist G., Gray M., caston L., Nag A., "Replication timing of genes and middle repetitive sequences", SCIENCE 224:686-692 (1984)	
AP	Grumbach M., Morishima A., Taylor J., "Human sex chromosome abnormalities in relation to DNA replication and heterochromatinization.", ROC NATL ACAD SCI USA, 49:581-589 (1963)	
AQ	Gunaratne, P., Nakao M., Ledbetter D., Sutcliffe J., Chinault A., "Tissue-specific and allele-specific replication timing control in the imprinted human Prader-Willi syndrome region", GENES & DEV 9:808-820 (1995)	
AR	Hatton K., Dhar V., Brown E., Iqbal M., Stuart S., Didamo V., Schidkraut C., "Replication program of active and inactive multigene families in mammalian cells", MOL CELL BIOL, 8:2149-2158 (1988)	
AS	Hollander G., Zuklys S., Morel C., Mizoguchi E., Mobisson K., Simpson S., Terhorst C., Wishart W., Golan Dhan A., burakoff S., "Monoclonal expression of the interleukin-2 locus", SCIENCE 279:2118-2121 (1998)	
AT	Holmquist G., "Role of replication time in the control of tissue specific gene expression" AM J HUM GENET 40:151-173 (1987)	
AU	Jackson A., Loeb L., "The mutation rate and cancer" GENETICS 148:1483-1490 (1998)	
AV	Kinzler K., Vogelstein B., "Colorectal tumors. THE METABOLIC AND MOLECULAR BASES OF AT INHERITED DISEASE, 7th ed. Vol. 1, Scriver C., Beaudet A., Sly W., Valle D., eds., McGraw-Hill, New York, pp. 643-663 (1995)	
AW	Kitsberg D., Selig S., Brandeis M., Simon I., Keshet I., Driscoll D., Nicholls R., Cedar H., "Allele-specific replication timing of imprinted gene regions," NATURE 364:459-463 (1993).	
AX	Knoll J., Cheng S., Lalande M., "Allele specificity of DNA replication timing in the Angelman/Prader-Willi syndrome imprinted chromosomal region," NAT GENET 6:41-46 (1994).	
AY	Knudson A., "Antioncogenes and human cancer," PROC NATL ACAD SCI USA 90:10914-10921 (1993).	
AZ	LaSalle J., Lalande M., "Domain organization of allele-specific replication within the GABRB3 gene cluster requires a biparental 15q1 1-13 contribution," NAT GENET 9:386-394 (1995).	
BA	Levanon D., Negreanu V., Bernstein Y., Bar-Am I., Avivi L., Groner Y., "AML1, AML2, and AML3, the human members of the runt domain gene-family: cDNA structure, expression, and chromosomal localization," GENOMICS 23:425-432 (1994).	
BB	Latt et al., "Patterns of late replication in X chromosomes of human Lymphoid cells," GENET CYTOGENET 3:171-181 (1981).	
BC	Levine, A., "p53, the cellular gatekeeper for growth and division," CELL 88:323-331 (1981).	
BD	Lima de Faria A., Jaworska H., "Late DNA synthesis in heterochromatin," NATURE 217:13 8-142 (1968).	

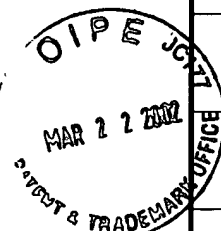
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BE	Linehan W., Lerrnan M., Zbar B., "Identification of the VHL gene: its role in renal cancer," JAMA. Vol. 273, No. 7, pp. 564-570 (1995).
BF	Litmanovitch T., Altaras M., Dotan A., Avivi L., "Asynchronous replication of homologous α -satellite DNA loci in man is associated with non-disjunction," CYTOGENET CELL GENET 81:26-35 (1998).
BG	Loeb L., "Mutator phenotype may be required for multistage carcinogenesis," CANCER RES 51:3075-3079 (1991).
BH	Look T., "Genes altered by chromosomal translocations in leukemia and lymphomas," THE GENETIC AT BASIS OF HUMAN CANCER, Vogelstein B., Kinder K., eds., McGraw-Hill, New York, pp. 109-141 (1998).
BI	Miller O., Schnedl W., Allen J., Erlanger B., "5-Methylcytosine localized in mammalian constitutive heterochromatin," NATURE 251:636-637 (1974).
BJ	Miller O., "Is the centromeric heterochromatin of <i>Mus musculus</i> late replicating?," CHROMOSOMA 55: 165-170 (1976).
BK	Mukherjee A., Murty V., Chaganti R., "Detection of cell-cycle stage by fluorescence in situ hybridization: its application in human interphase cytogenetics," CYTOGENET CELL GENET 68:1-94 (1992)
BL	Ohlsson R., Tycko B., Sapienza C., "Monoallelic expression: there can only be one," TIG Vol. 14, No. 11, pp. 435-438 (1967).
BM	Priest J., Heady J., Priest R., "Delayed onset of replication of human X chromosomes," J CELL BIOL, 35:483-487 (1967).
BN	Randhawa G., Cui H., Barletta J., Strichman-Almashanu L., Talpaz M., Kantalian H., Deisseroth A., Champlin R., Feinberg A., "Loss of imprinting in disease progression in chronic myelogenous leukemia," BLOOD Vol. 91, No. 9, pp. 3144-3147 (1998).
BO	Selig S., Ariel M., Goitein R., Marcus M., Cedar H., "Regulation of mouse satellite DNA replication time," EMBO J Vol. 7, no. 2, pp. 419-426 (1988).
BP	Selig S., Okumura K., Ward D., Cedar H., "Delineation of DNA replication time zones by fluorescence <i>in situ</i> hybridization." EMBO J Vol. 11. no. 3, pp. 1217-1225 (1992).
BQ	Smrzka O., Fae I., Stoger R., Kurzbauer R., Fischer G., Henn T., Weith A., Barlow D., "Conservation of maternal-specific methylation signal at the human IGF2R locus," HUM MOL GENET, Vol. 4, No. 10, pp. 1945-1952 (1995).
BR	Taylor J., "Asynchronous duplication of chromosomes in cultured cells of Chinese hamster," J BIOPHYS BIOCHEM CYTOL, 7:455-464 (1960).
BS	Ten Hagen K., Gilbert D., Willard H., Cohen S., "Replication timing of DNA sequences associated with human centromeres and telomeres," MOL CELL BIOL 10:6348-6355 (1990).
BT	Torchia B., Call L., Migeon B., "DNA replication analysis of FMRI, XIST, and factor 8C loci by FISH shows nontranscribed X-linked genes replicate late.," AM J HUM GENET 55:96-104 (1994).
BU	White, L., Rogan P., Nicholls R., Wu B., Korf B., Knoll J., "Allele-specific replication of 15q11-q13 loci: a diagnostic test for detection of uniparental disomy," AM J HUM GENET 59:423-430 (1996).

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BV	Willard H., Lad S., "Analysis of deoxyribonucleic acid replication in human X chromosomes by fluorescence microscopy," AM J HUM GENET 28:213-227 (1976).	
BW	Yeshaya J., Shaigi R., Shohat M., Avivi L., "FISH-detected delay in replication timing of mutated FMRI AT alleles on both active and inactive X-chromosomes," HUM GENET (in press) (1999).	
BX	Dotan et al., "Numerical chromosome aberrations in non-malignant cells derived from children suffering from different neoplasias", AMERICAN JOURNAL OF HUMAN GENETICS, 49(4)1312 (1991)	
BY	Bar-am et al., "Numerical chromosome aberrations in non-malignant lymphocytes derived from patients suffering from different types of neoplasia", JOURNAL OF CANCER RESEARCH AND CLINICAL ONCOLOGY, 116(Suppl., Part I):S 1-772 (1990)	
BZ	Bar-Am et al., "Increased level of aneuploidy in peripheral blood lymphocytes derived from patients with prostate cancer", UROLOGICAL RESEARCH, 21(6)P61 (1993)	
CA	Mukamel et al., "The effect of bilateral orchiectomy on the behavior of PHA-stimulated lymphocytes in patients with prostatic cancer", THE JOURNAL OF UROLOGY, 516A (1989)	
CB	Amiel et al., "Asynchronous replication of p53 and 21q22 loci in chronic lymphocytic leukemia", HUM GENET, 101:219-222 (1997)	
CC	Amiel et al., "Replication pattern of the p53 and 21q22 loci in the premalignant and malignant stages of carcinoma of the cervix", AMERICAN CANCER SOCIETY, 1965-1971 (1998)	
CD	Amiel et al., "Temporal differences in replication timing of homologous loci in malignant cells derived from CML and lymphoma patients", GENES, CHROMOSOMES & CANCER 22:225-231 (1998)	
CE	Dotan et al., "Modification in the inherent mode of allelic replication in lymphocytes of patients suffering from renal cell carcinoma: A novel genetic alteration associated with malignancy", GENES, CHROMOSOMES & CANCER, 27:270-277 (2000)	
CF	Amiel et al., "Replication status as a marker for predisposition for lymphoma in patients with chronic hepatitis C with and without cryoglobulinemia", EXPERIMENTAL HEMATOLOGY, 1-5 (2000)	
CG	Tockman et al., "Considerations in bringing a cancer biomarker to clinical application", CANCER RESEARCH (SUPPL.) 52:2711s-2718s (1992)	
CH	Amiel et al., "Asynchronous replication of allelic loci in Down Syndrome", EUROPEAN JOURNAL OF HUMAN GENETICS, 6:359-364 (1998)	

Examiner
Signature

Date
Considered

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